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FOREWORD

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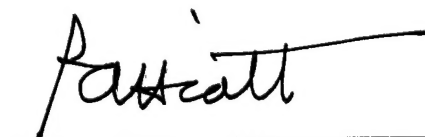
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Introduction

To date, there has been little research on appropriate education strategies for women interested in testing for inherited susceptibility to breast cancer, but who are at low to moderate risk based on family history of cancer. Information about interest in and attitudes toward testing is especially scarce for women from minority populations and those of lower socioeconomic status. This project was designed to develop and test appropriate and effective education and counseling measures for women from different ethnic groups at low to moderate risk. The project includes the following elements: 1) A survey of the prevalence of knowledge, attitudes, and intentions with regard to testing for inherited susceptibility to breast cancer among a racially and ethnically diverse stratified random sample of 16,795 women within the well-defined population served by Kaiser Permanente Medical Care Program (KPMCP). 2) Focus groups will be used to further explore and define possible ethnic group differences in attitudes toward genetic testing. 3) Results of focus groups and initial questionnaire will be used to refine and extend information collected from an ethnically-stratified sample of 1,200 African American, Latina, Asian, and white women at low to moderate risk (based on family history) 4) A randomized controlled trial will be conducted to compare three educational strategies. The trial will include 600 women, with equal numbers of African American, Asian, Latina, and white women in each arm.

Body

This study design represents a change from the initial proposal, in which we planned to identify and study unaffected family members of individuals with breast or ovarian cancer. The current design involves identification and study of a stratified random sample of all women health plan members. As indicated in our letter dated 12/18/96 informing DOD of the change, the new study design will allow a more meaningful evaluation of the current level of knowledge of and interest in genetic testing in the general population than would have been achieved by sampling only the relatives of women who had been diagnosed with breast or ovarian cancer.

During the first year of the study a short questionnaire was developed and pilot tested for use with the new study design. Data obtained in the questionnaire include personal and family history of breast and ovarian cancer, screening practices, knowledge of and attitudes toward inherited susceptibility for breast or ovarian cancer, testing for same, and sociodemographic information including ethnicity, religion, education, and occupation. Information on race and ethnicity is not routinely available for all health plan members. In order to draw an ethnically balanced sample, home addresses for women health plan members ages 25-70 years were geocoded by 1990 Census block. These codes were linked to data on the representation of specific ethnic groups in each census block. From the 386,123 geocoded health plan members, a probability sample of 16,795 women was drawn that was designed to have equal representation of the four race/ethnic groups under study, and which allowed for predicted response rates to the questionnaire (conservatively estimated at 50%), and prevalence of any family history of breast or ovarian cancer (estimated at 20%).

The short questionnaire (see Appendix 1) has recently been sent to the selected sample of women, and follow-up of questionnaire returns is ongoing. Focus groups have been planned to gather further information that will inform both the extended questionnaire and the design of the education strategies. Subsamples of survey respondents will be selected to constitute these focus groups.

Work has begun on the development of the extended questionnaire. In consultation with Drs. Beth Newman and Caryn Lerman, we have gathered relevant materials and questionnaires used in other studies. The extended questionnaire will obtain information on non-genetic risk factors for breast and ovarian cancers, knowledge of and attitudes toward risk associated with ethnic group membership and age, screening history and behavior, detailed questions concerning attitudes toward cancer, its prevention and treatment, as well as more detailed questions concerning attitudes toward inherited susceptibility to cancer and preferences regarding information about testing for inherited susceptibility. The questionnaire will also include brief, standardized measures of psychological and physical functioning, social networks and support, and general health status.

In the trial, we planned to compare educational strategies involving individual counseling by a genetic counselor, group sessions led by a genetic counselor, and prepared educational materials as the means for delivering information about testing for inherited susceptibility to breast and ovarian cancers. These approaches will be modified based on results from the surveys and the feasibility of various approaches within the health plan setting at the time in of the intervention. Cultural tailoring of the educational message will be incorporated into all three interventions. The effectiveness of the three educational approaches will be judged by outcomes that include knowledge and intentions toward genetic testing and screening behavior, client satisfaction, costs of the intervention, and utilization of medical services.

Work in progress: Returned surveys are being processed and the data entered. We are conducting parallel discussions of content of focus groups, as well as content and design of the extended questionnaire

Conclusions:

None yet

References:

None

UNDERSTANDING BREAST CANCER AND FAMILIES
CONFIDENTIAL

The purpose of this questionnaire is to help us understand how women think about breast cancer, and how their experiences affect those thoughts. There are no right or wrong answers to these questions; please just report what best describes your situation.

Your responses to these questions will be kept completely confidential.

Before starting this questionnaire, please check the information on the label above. If there are errors, please cross out the wrong information on the label and write in the correct information.

1. What is your date of birth?

____ / ____ / ____
MM DD YY

2. Compared to other women your age, would you say your health is:

1 ☐ Poor 2 ☐ Fair 3 ☐ Good 4 ☐ Very good 5 ☐ Excellent

These next questions are about breast care, and about breast conditions you may have had.

3. During the past two years, how many times did a physician or other health care professional conduct a breast exam on you?

1 ☐ Never 2 ☐ Once 3 ☐ Twice 4 ☐ Three or more times 5 ☐ Don't know

4. During the past two years, did you do a breast exam on yourself? (That is, have you ever felt your own breasts the way a doctor or nurse does to look for lumps or changes?)

1 ☐ Yes →
2 ☐ No
3 ☐ Don't know

How often did you conduct a breast exam on yourself in the last two years?

1 ☐ Less than once a year 4 ☐ About once a month
2 ☐ About once or twice a year 5 ☐ More often than once a month
3 ☐ Every 2 to 3 months

5. A mammogram is an x-ray of the breast taken by a machine that presses against the breasts while the picture is taken. Have you ever had one?

1 ☐ Yes →
2 ☐ No → Skip to question 7
3 ☐ Don't know

About how long has it been since you had your last mammogram?

1 ☐ 1 year ago or less 3 ☐ More than 2 years ago
2 ☐ Between 1-2 years ago

6. Women have mammograms either because of a problem, like a lump, or for a check-up. What was the reason for your last mammogram?

1 ☐ A problem (such as a lump, pain or discharge) 2 ☐ A check-up 3 ☐ Don't know

7. Have you ever had a breast biopsy? (Please include surgical and needle biopsies as well as needle aspirations.)

1 ☐ Yes →
2 ☐ No
3 ☐ Don't know

How many biopsies have you had? _____

The following questions are about your blood relatives (that is not including family members who are adopted or married into the family) and any breast or ovarian cancer they may have had. Please answer all the questions, even if no one in your family has ever been diagnosed with breast or ovarian cancer. Please include information about all of your relatives, even if they are deceased.

8. Has your mother ever been diagnosed with breast or ovarian cancer?

- 1 ☐ Yes →
 2 ☐ No
 3 ☐ Don't know

a. Did she have breast cancer, ovarian cancer or both?

1 ☐ Breast cancer 2 ☐ Ovarian cancer 3 ☐ Both

b. How old was she when she was first diagnosed? _____ years old

9. Has your maternal grandmother (mother's mother) ever been diagnosed with breast or ovarian cancer?

- 1 ☐ Yes →
 2 ☐ No
 3 ☐ Don't know

a. Did she have breast cancer, ovarian cancer or both?

1 ☐ Breast cancer 2 ☐ Ovarian cancer 3 ☐ Both

b. How old was she when she was first diagnosed? _____ years old

10. Has your paternal grandmother (father's mother) ever been diagnosed with breast or ovarian cancer?

- 1 ☐ Yes →
 2 ☐ No
 3 ☐ Don't know

a. Did she have breast cancer, ovarian cancer or both?

1 ☐ Breast cancer 2 ☐ Ovarian cancer 3 ☐ Both

b. How old was she when she was first diagnosed? _____ years old

11. a. How many sisters and half-sisters do you have? _____ sisters _____ half-sisters
If you have no sisters or half-sisters, please skip to question 12

b. Have any of your sisters or half-sisters ever been diagnosed with breast cancer?

- 1 ☐ Yes →
 2 ☐ No
 3 ☐ Don't know

i. How many of your sisters?

ii. How many of your half-sisters?

iii. How many of your sisters were diagnosed before they were 50 years old?

iv. How many of your half-sisters were diagnosed before they were 50 years old?

c. Have any of your sisters or half-sisters ever been diagnosed with ovarian cancer?

- 1 ☐ Yes →
 2 ☐ No
 3 ☐ Don't know

i. How many of your sisters?

ii. How many of your half-sisters?

12. a. How many daughters do you have? _____ *If none, skip to Question 13*

b. Have any of your daughters ever been diagnosed with breast cancer?

- 1 ☐ Yes →
 2 ☐ No
 3 ☐ Don't know

i. How many of your daughters?

ii. How many of your daughters were diagnosed before they were 50 years old?

c. Have any of your daughters ever been diagnosed with ovarian cancer?

- 1 ☐ Yes →
 2 ☐ No
 3 ☐ Don't know

How many of your daughters?

13. Have any of your maternal aunts (your mother's sisters) ever been diagnosed with breast cancer?

- 1 ☐ Yes →
2 ☐ No
3 ☐ I have no maternal aunts
4 ☐ Don't know

i. How many of your maternal aunts?
ii. How many of your maternal aunts were diagnosed before they were 50 years old?

14. Have any of your female cousins on your mother's side of the family ever been diagnosed with breast cancer?

- 1 ☐ Yes →
2 ☐ No
3 ☐ I have no female cousins on this side
4 ☐ Don't know

i. How many of your cousins?
ii. How many of your cousins were diagnosed before they were 50 years old?

15. Have any of your paternal aunts (your father's sisters) ever been diagnosed with breast cancer?

- 1 ☐ Yes →
2 ☐ No
3 ☐ I have no paternal aunts
4 ☐ Don't know

i. How many of your paternal aunts?
ii. How many of your paternal aunts were diagnosed before they were 50 years old?

16. Have any of your female cousins on your father's side of the family ever been diagnosed with breast cancer?

- 1 ☐ Yes → →
2 ☐ No
3 ☐ I have no female cousins on this side
4 ☐ Don't know

i. How many of your cousins?
ii. How many of your cousins were diagnosed before they were 50 years old?

17. Have any of your aunts or female cousins ever been diagnosed with ovarian cancer?
(Please include your paternal and maternal aunts, and female cousins on both sides of the family.)

- 1 ☐ Yes →
2 ☐ No
3 ☐ I have no aunts or female cousins
4 ☐ Don't know

How many of your aunts and female cousins?

18. Do you have any male relatives who have ever been diagnosed with breast cancer

- 1 ☐ Yes →
2 ☐ No
3 ☐ Don't know

Which relatives?

19. Have any close friends been diagnosed with breast or ovarian cancer?

- 1 ☐ No 2 ☐ Yes, breast cancer 3 ☐ Yes, ovarian cancer 4 ☐ Yes, both 5 ☐ Don't know

20. Have you ever been told by a doctor that you had breast or ovarian cancer?

- 1 ☐ Yes →
2 ☐ No
3 ☐ Don't know

a. Were you told you had breast cancer, ovarian cancer or both?

1 ☐ Breast cancer 2 ☐ Ovarian cancer 3 ☐ Both

b. How old were you when you were first diagnosed? _____ years old

↓
Skip to question 27

The next few questions ask for your thoughts and opinions..

21. How frequently do you think about getting breast cancer?

- 1 ☐ Never 2 ☐ Rarely 3 ☐ Sometimes 4 ☐ Often 5 ☐ All the time

22. In your opinion, compared to other women your age, what are your chances of getting breast cancer?

- 1 ☐ Much lower 2 ☐ A little lower 3 ☐ About the same 4 ☐ A little higher 5 ☐ Much higher

23. In your opinion, what are the chances that women with your family history of breast cancer will develop breast cancer?

- 1 ☐ Much lower chance 2 ☐ A little lower chance 3 ☐ About the same 4 ☐ A little higher chance 5 ☐ Much higher chance

24. In your opinion, what are the chances that women of your racial or ethnic background will get breast cancer, compared to women in general?

- 1 ☐ Much lower chance 2 ☐ A little lower chance 3 ☐ About the same 4 ☐ A little higher chance 5 ☐ Much higher chance

25. Compared to other health problems or diseases, how much do you worry about breast cancer?

- 1 ☐ Not at all 2 ☐ A little bit 3 ☐ Some 4 ☐ Quite a bit 5 ☐ A great deal

26. How do you react to information about breast cancer in the media (such as radio, TV or magazines)?

- 1 ☐ Avoid it so you won't have to worry about breast cancer
2 ☐ Ignore it because it doesn't concern you
3 ☐ Watch, listen or read to learn more

27. Have you ever spoken with a health care professional about your family history of breast cancer?

- 1 ☐ Yes
2 ☐ No
3 ☐ Don't know

Who did you speak with? (Check all that apply.)

- 1 ☐ Primary care provider 3 ☐ Geneticist/genetic counselor
2 ☐ Nurse practitioner 4 ☐ Other (Please specify) _____

28. How do you feel about your knowledge of breast cancer right now?

- 1 ☐ I need a lot more information 3 ☐ I have enough information
2 ☐ I need a little more information 4 ☐ I have too much information

The next questions ask about some recent breast cancer research you may have heard about.

29. How much have you read or heard about genetic testing for breast cancer?

- 1 ☐ Almost nothing 2 ☐ Relatively little 3 ☐ A fair amount 4 ☐ A lot

30. Genetic testing for inherited risk of breast cancer is now possible for some people. If a blood test could tell you how likely it is that you will get breast cancer (again), would you be interested in taking that test?

- 1 ☐ Yes
2 ☐ No
3 ☐ Don't know

If the blood test could tell you about your chances of getting breast cancer, but if you could not prevent the disease, would you still be interested in taking the test?

- 1 ☐ Yes 2 ☐ No 3 ☐ Don't know

These final questions ask for some background information about you.

31. What is your current marital status?

- 1 ☐ Single, never married
- 2 ☐ Married or living as married
- 3 ☐ Separated or divorced
- 4 ☐ Widowed

32. What is your race/ethnicity? (Check all that apply)

- 1 ☐ White
- 2 ☐ Black/African-American
- 3 ☐ Hispanic/ Latina
- 4 ☐ Chinese
- 5 ☐ Japanese
- 6 ☐ Other Asian
- 7 ☐ Pacific Islander
- 8 ☐ Native American
- 9 ☐ Other (Specify _____)

33. Do you prefer to read or speak a language other than English?

- 1 ☐ Yes →
- 2 ☐ No
- 3 ☐ Don't know

What language do you prefer?

- 1 ☐ Spanish
- 2 ☐ Cantonese
- 3 ☐ Tagalog
- 4 ☐ Other (Please specify _____)

34. What is your religious background?

- 1 ☐ Buddhist
- 2 ☐ Catholic
- 3 ☐ Hindu
- 4 ☐ Jewish
- 5 ☐ Protestant
- 6 ☐ Muslim
- 7 ☐ None
- 8 ☐ Other (Please specify _____)

35. Please indicate the highest grade that you completed in school. (Circle one number)

K 1 2 3 4 5 6 7 8

GRADE SCHOOL

9 10 11 12

HIGH SCHOOL

13 14 15 16

COLLEGE OR
TECHNICAL SCHOOL

17+

GRADUATE OR
PROFESSIONAL SCHOOL

36. This questionnaire is part of a study of what women think about breast cancer and testing for inherited risk. We will be inviting some of the women who have completed this questionnaire to take part in other parts of the study. May we contact you to tell you more about the study?

- 1 ☐ Yes, please
- 2 ☐ No, thank you

Many thanks for taking the time to complete this questionnaire!